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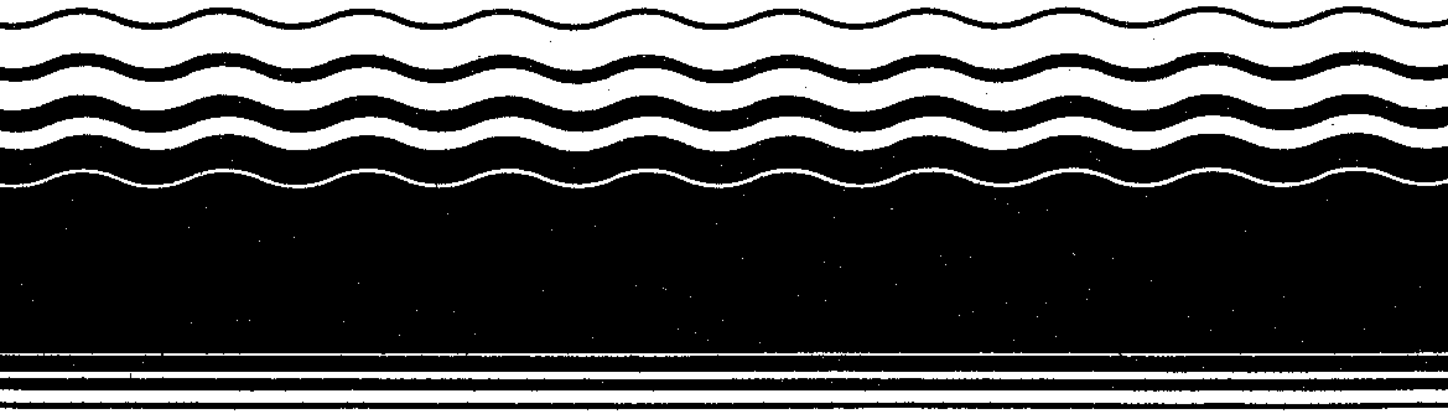
Guidance for Data Useability in Risk Assessment (Part A)

Final



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Guidance for Data Useability in Risk Assessment (Part A)

Final

Notice: Guidance for Radioanalytical Data Useability in Risk Assessment is Given in Part B

Office of Emergency and Remedial Response
U.S. Environmental Protection Agency
Washington, DC 20460

NOTICE

The policies and procedures set forth here are intended as guidance to U.S. Environmental Protection Agency and other government employees. They do not constitute rulemaking by the Agency, and may not be relied on to create a substantive or procedural right enforceable by any other person. The U.S. Environmental Protection Agency may take action that is at variance with the policies and procedures in this guidance and may change them at any time without public notice.

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National Technical Information Service
5285 Port Royal Road
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Phone: 703-487-4650

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Tips*

- *The analytical data objective for baseline risk assessments is that uncertainty is known and acceptable, not that uncertainty be reduced to a particular level. (p. 3)*
- *To maximize data useability for the risk assessment, the risk assessor must be involved from the start of the RI. (p. 7)*
- *All data can be used in the baseline risk assessment as long as their uncertainties are clearly described. (p. 11)*
- *Uncertainty in the analytical data, compounded by uncertainty caused by the selection of the transport models, can yield results that are meaningless or that cannot be interpreted. (p. 14)*
- *Uncertainties in toxicological measures and exposure assessment are often assumed to be greater than uncertainties in environmental analytical data; thus, they are assumed to have a more significant effect on the uncertainty of the risk assessment. (p. 17)*
- *Analytical data collected solely for other purposes may not be of optimal use to the risk assessment. (p. 20)*
- *Effective planning improves the useability of environmental analytical data in the final risk assessment. (p. 25)*
- *Use historical analytical data and a broad spectrum analysis to initially identify the chemicals of potential concern or exposure areas. (p. 26)*
- *To expedite the risk assessment, preliminary data should be provided to the risk assessor as soon as they are available. (p. 35)*
- *To protect human health, place a higher priority on preventing false negatives in sampling and analysis than on preventing false positives. (p. 41)*
- *Use preliminary data to identify chemicals of potential concern and to determine any need to modify the sampling or analytical design. (p. 41)*
- *Specific analysis for compounds identified during library search can be requested. (p. 41)*
- *The closer the concentration of concern is to the detection limit, the greater the possibility of false negatives and false positives. (p. 47)*
- *The wide range of chemical concentrations in the environment may require multiple analyses or dilutions to obtain useable data. Request results from all analyses. (p. 47)*
- *Define the type of detection or quantitation limit for reporting purposes; request the sample quantitation limit for risk assessment. (p. 47)*
- *When contaminant levels in a medium vary widely, increase the number of samples or stratify the medium to reduce variability. (p. 50)*
- *Sampling variability typically contributes much more to total error than analytical variability. (p. 50)*
- *Field methods can produce legally defensible data if appropriate method QC is available and if documentation is adequate. (p. 57)*
- *To minimize the potential for false negatives, obtain data from a broad spectrum analysis from each medium and exposure pathway. (p. 58)*
- *The CLP or other fixed laboratory sources are most appropriate for broad spectrum analysis or for confirmatory analysis. (p. 58)*
- *Solicit the advice of the chemist to ensure proper laboratory selection and to minimize laboratory and/or methods performance problems that occur in sample analysis. (p. 58)*
- *Use of the Sampling Design Selection Worksheet will help the RPM or statistician determine an appropriate sampling design. (p. 65)*

* For further information, refer to the text. Page numbers are provided.

Tips
(cont'd)

- *While other designs may be appropriate in many cases, stratified random or systematic sampling designs are always acceptable. (p. 65)*
- *If the natural variability of the chemicals of potential concern is large (e.g., greater than 30%), the major planning effort should be to collect more environmental samples. (p. 72)*
- *At least one broad spectrum analytical sample is required for risk assessment, and a minimum of two or three are recommended for each medium in an exposure pathway. (p. 73)*
- *Collect and analyze background samples prior to the final determination of the sampling design since the number of samples is significantly reduced if little background contamination is present. (p. 75)*
- *Systematic sampling supplemented by judgmental sampling is the best strategy for identifying hot spots. (p. 75)*
- *Focus planning efforts on maximizing the collection of useable data from critical samples. (p. 78)*
- *The ability to combine data from different sampling episodes or different sampling procedures is a very important consideration in selecting a sampling design but should be done with caution. (p. 78)*
- *Ensure that critical requirements and priorities are specified on the Method Selection Worksheet so that the most appropriate methods can be considered. (p. 83)*
- *Use routine methods wherever possible since method development is time-consuming and may result in problems with laboratory implementation. (p. 83)*
- *Analyte-specific methods that provide better quantitation can be considered for use once chemicals of potential concern have been identified by broad spectrum analysis. (p. 84)*
- *All results should be reported for samples analyzed at more than one dilution. (p. 85)*
- *Field analysis can be used to decrease cost and turnaround time providing data from a broad spectrum analysis are available. (p. 89)*
- *Focus corrective action on maximizing the useability of data from critical samples. (p. 97)*
- *Use preliminary data as a basis for identifying sampling or analysis deficiencies and taking corrective action. (p. 100)*
- *Problems in data useability due to sampling can affect all chemicals involved in the risk assessment; problems due to analysis may only affect specific chemicals. (p. 100)*
- *Qualified data can usually be used for quantitative risk assessments. (p. 105)*
- *Anticipate the need to combine data from different sampling events and/or different analytical methods. (p. 107)*
- *Determine the distribution of the data before applying statistical measures. (p. 109)*
- *Determine the statistical measures of performance most applicable to site conditions before assessing data useability. (p. 110)*
- *Use data qualified as U or J for risk assessment purposes. (p. 113)*
- *The major concern with false negatives is that the decision based on the risk assessment may not be protective of human health. (p. 117)*
- *False negatives can occur if sampling is not representative, if detection limits are above concentrations of concern, or if spike recoveries are very low. (p. 117)*
- *False positives can occur when blanks are contaminated or spike recoveries are very high. (p. 118)*
- *Statistical analysis may determine if site concentrations are significantly above background concentrations when the differences are not obvious. (p. 120)*
- *The primary planning objective is that uncertainty levels are acceptable, known and quantitatable, not that uncertainty be eliminated. (p. 121)*

PREFACE

The U.S. Environmental Protection Agency (EPA) has established a Data Useability Workgroup to develop national guidance for determining data useability requirements needed for environmental data collection on hazardous waste sites under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA). Data useability is the process of assuring or determining that the quality of data generated meets the intended use. This guidance has been designed by the Risk Assessment Subgroup of the Data Useability Workgroup to provide data users with a nationally consistent basis for making decisions about the minimum quality and quantity of environmental analytical data that are sufficient to support Superfund risk assessment decisions, regardless of which parties conduct the investigation. This document is the first part (Part A) of the two-part *Guidance for Data Useability in Risk Assessment*. Part B of this guidance addresses radioanalytical issues.

Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual, Part A (EPA 1989a) serves as a general guidance document for the risk assessment process. Building upon RAGS, an "interim final" version of *Guidance for Data Useability in Risk Assessment* was issued by the Risk Assessment Subgroup of the Data Useability Workgroup in October 1990. The guidance was issued as "interim final" in order to obtain and incorporate comments and criticisms from data users who tested it in real-world situations.

The authors acknowledge the significant help of all who have provided comments and criticisms. The results indicate that many people react favorably to the guidance and find it useful in planning a risk assessment or in evaluating assessments already underway. Issues were identified where guidance in the interim final needed to be supplemented or discussed in more detail. These issues include providing a more detailed discussion of sampling strategies, incorporating groundwater factors, addressing soil depth for exposure, and obtaining background data. Issues concerning data reporting formats, validation and use of non-CLP data, and tentatively identified compounds were also identified. The final version of the guidance provides greater detail in the discussion of these and other issues.

This guidance provides direction for planning and assessing analytical data collection activities for the baseline human health risk assessment, conducted as part of the remedial investigation (RI) process. **Although the guidance addresses the baseline risk assessment within the RI, it is appropriate for use in the new Superfund Accelerated Cleanup Model (SACM) where data needs for risk assessment are considered at the onset of site evaluation.** Site-specific conditions may often require sampling or analysis beyond the basic recommendations given in this guidance. The guidance does not directly address the use of ecological data for purposes other than baseline risk assessments for human health, although some considerations have been included when data may be used for both ecological and human health evaluation.

This guidance complements guidance provided in RAGS (EPA 1989a), *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988a), and *Data Quality Objectives for Remedial Response Activities: Development Process* (EPA 1987a). RAGS provides the framework for making data quality assessments in baseline risk assessments, and this guidance supplements and strengthens important technical details of the framework by providing direction on minimum requirements for environmental analytical data used in baseline risk assessments. As such, it complements and builds upon Agency guidance for the development and use of data quality objectives in all data collection activities.

This guidance is addressed primarily to the remedial project managers (RPMs) who have the principal responsibility for leading the data collection and assessment activities that support the human health risk assessment and, secondarily, to risk assessors who must effectively communicate their data needs to the RPMs and use the data provided to them. Chemists, quality assurance specialists, statisticians, hydrogeologists and other technical experts involved in the RI process can use this guidance to optimize the useability of data collected in the RI for use in baseline risk assessments.

Comments on the guidance should be sent to:

Toxics Integration Branch
Office of Emergency and Remedial Response
401 M Street, SW (OS-230)
Washington, DC 20460
Phone: 202-260-9486

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This guidance was developed by an EPA workgroup with membership from EPA Headquarters, EPA Regional offices and representatives of the contractor community. The EPA Risk Assessment Subgroup of the Data Useability Workgroup provided valuable input regarding the content, approach and organization of the guidance. Members of the Risk Assessment Subgroup, responsible for generating this guidance, have experience in human health risk assessment, remedial project management, chemistry, toxicology, hydrogeology, and quality assurance. Technical review was provided by toxicologists, chemists, quality assurance specialists, engineers, project managers, and statisticians from both EPA and contractor staff.

Leadership for development of the "interim final" version of this guidance was provided by Data Useability Workgroup Region III Co-chairpersons Chuck Sands [currently at the Analytical Operations Branch (AOB)] and Claudia Walters, and Ruth Bleyler of the Toxics Integration Branch (TIB).

Leadership for development of the "final" version of this guidance was provided by Ruth Bleyler and Lisa Matthews of TIB and Chuck Sands of AOB. We wish to acknowledge Region V and Region VI for their assistance with the implementation effort for the final version of the guidance.

Members of the Risk Assessment Subgroup include:

Ruth Bleyler	Toxics Integration Branch
Richard Brunker	USEPA Region III
Rex Bryan	Viar & Company
Matt Charsky	Office of Waste Programs Enforcement
Skip Ellis	CH2M HILL
Gwen Hooten	USEPA Region VIII
Dawn Ioven	USEPA Region III
Peter Isaacson	Viar & Company
Cindy Kaleri	USEPA Region VI
Jim LaVelle	USEPA Region VIII
Jim Luey	USEPA Region VIII
Jon Rauscher	USEPA Region VI
Chuck Sands	Analytical Operations Branch
Robin Smith	CH2M HILL
Pat Van Leeuwen	USEPA Region V
Chris Weis	USEPA Region VIII
Leigh Woodruff	USEPA Region X

Additional Workgroup participation includes:

Wayne Berman	ICF
Ann Marie Burke	USEPA Region I
Dorothy Campbell	USEPA Region VIII
Judy Hsieh	USEPA Region I
Mark Moese	Ebasco
Sheila Sullivan	USEPA Region V
Hans Waetjen	Office of Waste Programs Enforcement